161

2877 DAC

213202.00361

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: K. Brown
JAMES SAMSOONDAR, ET AL.	)	
	:	Group Art Unit: 2877
Application No.: 10/056,205	)	
	:	
Filed: January 28, 2002	)	
	:	
For: METHOD AND APPARATUS FOR MEASURING ANALYTES IN BLOOD BAGS	)	
	:	December 16, 2003
	)	

Mail Stop Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

REQUEST FOR WITHDRAWAL OF ERRONEOUS NOTICE OF ABANDONMENT

Sir:

Based on the facts provided below, Applicants submit that the Notice of Abandonment for failure to pay the Issue Fee dated November 18, 2003 was erroneously issued by the U.S. Patent and Trademark Office.

A. On July 23, 2003, an Amendment was filed in the above-identified application in response to the Office Action mailed April 23, 2003.

B. On November 18, 2003, a Notice of Abandonment was mailed. The Notice indicates that no reply was received in response to the Office Action mailed April 23, 2003. The Notice also indicates that Attorney Richard P. Bauer informed the Examiner on November 17, 2003 that this case was

abandoned. Such an indication was in fact given to the Examiner, but the indication was made in error. Mr. Bauer called the Examiner back later on that same day (November 17, 2003), and indicated that the case was not abandoned. The Examiner informed Mr. Bauer that the Notice of Abandonment had already been mailed, and could not be recalled.

Copies of these papers are attached hereto.

CONCLUSION

Based on the above facts, and the attached documentation in support of the facts, Applicants submit that the Notice of Abandonment issued by the U.S. Patent and Trademark Office on November 18, 2003 was in error. Applicants respectfully request that the holding of abandonment for failure to timely file a reply to the April 23, 2003 Office Action be withdrawn.

As this application was abandoned because of an error by the Patent Office, no fee is believed necessary to revive this application.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address below.

Respectfully submitted,

Attorney for Applicants
Dawn C. Hayes
Registration No. 44,751

Patent Administrator
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street
Suite 1600
Chicago, Illinois 60661-3693
Facsimile: (312) 902-1061

Applicant: Sams Sconder, et al. Appln No: 10/056,205 Filing/Issue Date: 1/28/02

Docket No: 213202-0036 Atty/Sec: D. Hayes

Title: Method and Apparatus for Measuring Analytes in Blood Bags

Date Hand Carried to USPTO: 7/23/03 Due Date: 7/23/03

- ☑ Transmittal Form (1 pp)
- ☐ Patent Application Transmittal Form (___pp)
- ☑ Fee Transmittal, in duplicate (1 pp)
- ☐ Application Data Sheet (___pp)
- ☐ Specification (including claims & abstract) (___pp)
- ☐ Drawings ___ Formal ___ Informal (___sheets)
  - ☐ Submission of Drawings (___pp)
  - ☐ Request for Approval of Drawing Changes (___pp)
- ☐ Combined Oath/Declaration & Power of Atty (___pp)
- ☐ Declaration (___pp)
- ☐ Assignment with PTO-1595 (___pp)
- ☐ Non-Publication Request (___pp)
- ☐ Claim for priority (___pp)
  - ☐ with certified copies of ___ Priority Document(s)
- ☐ Sequence Listing and diskette
- ☐ Information Disclosure Stmt w/PTO 1449 (___pp)
  with ___ cited references
- ☐ Provisional Appln. Cover Sheet (___pp)
- ☐ RCE/CPA Transmittal (___pp)
- ☐ Response to Missing Parts w/copy of Notice (___pp)

- ☒ Amendment/Response (8 pp)
  - ☐ with Petition for ___-Month Extension of Time
  - ☐ Other:
- ☐ Affidavit(s)/Declaration(s) (___pp)
- ☐ Petition (___pp)
- ☐ Notice of Appeal (___pp)
- ☐ Appeal Brief (orig. plus 2) (___pp)
- ☐ Issue Fee Transmittal (___pp)
- ☐ Revocation of Power of Attorney (___pp)
- ☐ 3.73(b) Statement (___pp)
- ☐ Power of Attorney (___pp)
- ☐ Status Inquiry (___pp)
- ☐ Terminal Disclaimer (___pp)
- ☐ Request for Cert. of Correction w/PTO 1050 (___pp)
- ☑ Maintenance Fee Trans (___pp)
  - ☐ Fee Address Form (___pp)
- ☐ Other:
- ☐ Other:
- ☐ Check for $
- ☐ Authorized to Charge Deposit Acct $

OIPE JUL 23 2003 PATENT & TRADEMARK OFFICE

A USPTO DATE STAMP CONFIRMS RECEIPT OF THE ABOVE BY THE USPTO

RECEIVED DEC 29 2003 TECHNOLOGY CENTER 2800

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

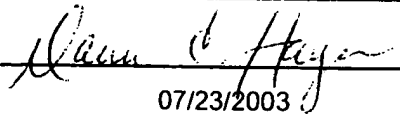
Application Number	10/056,205
Filing Date	01/28/2002
First Named Inventor	James SAMSOONDAR
Group Art Unit	2877
Examiner Name	K. Brown
Total Number of Pages in This Submission	8
Attorney Docket Number	213202.00361

ENCLOSURES *(check all that apply)*

- [x] Fee Transmittal Form
- [ ] Fee Attached
- [x] Amendment / Reply
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
- [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) *(please identify below)*:

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Dawn C. Hayes Registration No.: 44,751
Signature	
Date	07/23/2003

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: [ ]

Typed or printed name			
Signature		Date	

PTO/SB/17 (01-03)
Approved for use through 04/30/2003. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 0.00

Complete if Known	
Application Number	10/056,205
Filing Date	01/28/2002
First Named Inventor	James SAMSOONDAR
Examiner Name	K. Brown
Group Art Unit	2877
Attorney Docket No.	213202.00361

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account

Deposit Account Number: 50-1710

Deposit Account Name: KATTEN MUCHIN ZAVIS ROSENMAN

☑ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below	Fee Paid
Total Claims	8	-20** =	0	X	= 0.00
Independent Claims	2	- 3** =	0	X	= 0.00
Multiple Dependent					= 0.00

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840	1805	1,840*	Requesting publication of SIR after Examiner action	
2251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	1254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 0.00

SUBMITTED BY

Complete *(if applicable)*

Name *(Print/Type)*	Dawn C. Hayes	Registration No. *(Attorney/Agent)*	44,751	Telephone	202-625-3549
Signature	Dawn C. Hayes			Date	07/23/2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

213202.00361

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
JAMES SAMSOONDAR, ET AL.	)	Examiner: K. Brown
Application No.: 10/056,205	)	Group Art Unit: 2877
Filed: January 28, 2002	)	
For: METHOD AND APPARATUS FOR MEASURING ANALYTES IN BLOOD BAGS	)	July 23, 2003

Commissioner for Patents,
P.O. Box 1450
Alexandria VA 22313-1450

AMENDMENT

Sir:

In response to the Office Action mailed April 23, 2003, please amend the above-identified application as follows:

IN THE CLAIMS:

Please amend the claims to read as shown below:

1. (Currently Amended) A method for determining a concentration of ~~at least~~ one, or more than one analyte in a sample contained in a blood bag or in a tubing in fluid communication with said blood bag, using an instrument comprising ~~at least~~ one, or more than one calibration algorithm for said ~~at least~~ one, or more than one analyte, said method comprising:

a) irradiating said sample in said tubing, or said blood bag, using a radiation source of about 475 nm to about 2,700 nm;

b) measuring an absorbance ~~from~~ of said sample ~~for said at least one analyte~~; and

c) calculating a concentration of said ~~at least~~ one, or more than one analyte using said absorbance and said ~~at least~~ one, or more than one calibration algorithm.

2. (Currently Amended) The method of claim 1, wherein ~~in~~ said step of calculating (step c)) comprises ~~combines~~ determining values of first derivatives of ~~at least~~ two, or more than two portions of a spectrum generated from said ~~absorbance~~ step of measuring (step b), and incorporating said first derivatives into said one, or more than one calibration algorithm to provide said concentration.

3. (Original) The method of claim 1 wherein said blood bag, or said tubing is translucent and contains writing on its surface and irradiation is transmitted through said writing, said blood bag or said tubing, and said sample contained in said blood bag or said tubing.

4. (Original) The method of claim 1 wherein said step of irradiating (step a)) includes reflecting radiation from a reflective surface placed behind said blood bag or said tubing.

5. (Original) The method of claim 2 wherein in said step of measuring (step b)), light leakages are compensated for by measuring dark current for both sample and reference measurements.

6. (Currently Amended) The method of claim 2, wherein ~~the at least~~ said one, or more than one analyte is selected from the group consisting of haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked haemoglobin.

7. (Currently Amended) The method of claim ~~6~~1, wherein ~~in~~ said ~~step of measuring (step b)) said absorbance measurement for said at least~~ one, or more than one analyte is ~~incorporated into an algorithm~~ selected from the group consisting of haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue, and cross-linked haemoglobin~~, and a combination thereof, and said concentration of said one, or more than one analyte in said sample is determined~~.

8. (Currently Amended) A method for determining a concentration of one, or more than one of haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked haemoglobinin in a sample contained in a blood bag or in a tubing in fluid communication with said blood bag, using an instrument comprising one, or more than one calibration ~~algorithms~~ algorithm for each of said haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked haemoglobin, said method comprising:

a) irradiating said sample in said tubing or said blood bag using a radiation source of about 475 nm to about 2,700 nm;

b) measuring an absorbance ~~from~~ of said sample, ~~for said one, or more than one of haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked haemoglobin;~~ and

c) calculating a concentration for one, or more than one of said haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked

~~haemoglobinusing~~ haemoglobin by ~~said absorbance and said one or more calibration algorithms, by combining~~ determining values of first derivatives of ~~at least~~ two, or more than two portions of a spectrum generated from said ~~absorbance~~ step of measuring (step b), and incorporating said first derivatives into said one, or more than one calibration algorithm to provide said concentration.

Remarks

Reconsideration and allowance of the subject application are respectfully requested.

Claims 1-8 are pending in this application, with Claims 1 and 8 being independent. In this Amendment, Claims 1-2 and 6-8 have been amended. All amendments are being made for reasons of clarity with respect to the specification and drawings, and not for reasons relating to the statutory requirements for patentability.

Rejections under 35 U.S.C. 102

Claims 1-8 stand rejected under 35 U.S.C. 102 (e) as being anticipated by Fodgaard (U.S. Patent No. 5,817,007). Applicant respectfully traverses this rejection for the reasons set forth below.

Fodgaard discloses a method of determining the concentration of a blood constituent that involves extracting a stream of blood, at a flow rate of 50-1,000 ml/min, and directing this whole blood stream through a flow-through measuring cuvette having an optically transparent surface part, and then irradiating the optically transparent surface part of the flow-through measuring cuvette with multi-wavelength near infrared (NIR) light. This is followed by detecting, and quantifying the concentration of the blood constituent. (See, for example, Col. 1, line 66 to Col. 2, line 22.)

The method of Fodgaard differs from the presently claimed method for at least the reason that it involves irradiating a stream of blood within a *flow-through* cuvette (see item 24 in Figures 1, 4 and 14; or item 90 in Figures 5 and 6). In Col. 8, lines 41-43, it is stated that the cuvette "constitutes a central or essential component of the whole blood analyzing apparatus." This method does not detect constituents of blood located within a blood bag, or within tubing in fluid communication with the blood bag, as set forth in the present claims. Furthermore, there is no teaching or suggestion

within Fodgaard that a blood bag, or tubing in fluid communication with a blood bag, can be used in place of a flow-through cuvette.

The methods claimed in Claims 1-8 are therefore novel in view of Fodgaard, and Applicant respectfully requests that the rejection under 35 U.S.C. 102(e) be withdrawn. Furthermore, Applicant submits that the features of at least Claim 1 are also not suggested in Fodgaard, and that one of skill in the art would not have been directed to the methods presently claimed upon reading Fodgaard as there is no suggestion that the flow-through cuvette may be replaced with the blood bag or associated tubing. Therefore, it is submitted that Claim 1, and dependent Claims 2-8, are also not obvious in view of Fodgaard.

Claims 1-4 and 6-8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bonner (U.S. Patent No. 4,522,494). Applicant respectfully traverses this rejection for the reasons set forth below.

Bonner discloses a method for determining the platelet concentration in plasma contained in a transfusion bag by producing a periodic laminar flow within the blood bag to assist in orienting the platelets and allowing the platelets to become randomized, followed by irradiating the sample with a HeNe laser and measuring, at a selected scattering angle, the scattered light intensity of the plasma. The concentration of platelets in the plasma is then determined using a computer program. (See, for example, Col. 2, lines 6-29.)

The method of Bonner differs from the method of the present claims for at least the reason that it involves determining a scattered light intensity of *non-aggregated platelets* contained in a transfusion bag, rather than an absorbance of an *analyte* in a blood bag. The term "analyte" is defined within the present specification on page 13, line 13, as a chemical component, and may include hemoglobin, bilirubin, biliverdin, Intralipid™, methylene blue, cross-linked hemoglobin, and other analytes. There is no

teaching or suggestion in Bonner that the disclosed method may be used to determine the concentration of an analyte in a blood bag as claimed in the present invention. Furthermore, an absorbance value of a plasma sample cannot be used to determine the concentration of platelets in a plasma sample according to the method of Bonner, as the method of Bonner uses a computer program that requires a scattered light intensity value. Additionally, the method of Bonner involves periodic agitation of the blood within the blood bag during a measurement cycle in order to ensure that the concentration of non-aggregated platelets is determined. (See Col. 2, lines 30-32.) Such a step is not required for the determination of an analyte in blood bag according to the presently claimed invention.

Applicant submits that Claims 1-4 and 6-8 are, therefore, novel over Bonner, and respectfully requests that the rejection of Claims 1-4 and 6-8 under 35 U.S.C. 102(b) be withdrawn. Furthermore, Applicant submits that the features of Claim 1 are not suggested in Bonner, and that one of skill in the art would not have been directed to the presently claimed methods upon reading of Bonner, as there is no suggestion that the absorbance of an analyte may be determined. Therefore, it is also submitted that Claim 1, and the claims that depend from Claim 1, are not obvious in view of Bonner.

Rejections under 35 U.S.C. 103

Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Bonner (U.S. Patent No. 4,522,494) in view of Weythman (U.S. Patent No. 4,128,830). Applicant respectfully traverses this rejection for the reason set forth below.

As argued above, the method of Bonner differs from the method of the present claims. For example, the method of Bonner involves determining platelet concentration using scattered light intensity of a sample contained in a transfusion bag, rather than the concentration of an analyte using absorbance. There is no suggestion in Bonner that the concentration of an analyte may be determined by measuring

absorbance. This deficiency of Bonner is not remedied by combination with Weythman, which discloses compensating a signal for light sensors. There is no disclosure or suggestion in Weythman of determining the concentration of an analyte in a blood bag by measuring absorption.

Applicant further submits that Claim 5 depends from Claim 1, and therefore incorporates the features of Claim 1, none of which are disclosed or suggested by Bonner and Weythman, either alone or in combination. The claims of this application are, therefore, inventive over the combination of Bonner and Weythman, and Applicant respectfully requests that this rejection of Claim 5 under 35 U.S.C. 103(a) be withdrawn.

In view of the amendments and remarks set forth above, Applicant submits that this application is in condition for allowance, and respectfully requests prompt issuance of a notice thereof.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

Attorney for Applicant
Dawn C. Hayes
Registration No. 44,751

PATENT ADMINISTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street
Suite 1600
Chicago, Illinois 60661-3693
Facsimile: (312) 902-1061